DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 1 3 2001

Borek Janik, Ph.D.
Official Correspondent
Sebia
c/o Morax
13805 Waterloo
Chelsea, MI 48118

Re: 510(k) Number: K011113
Trade/Device Name: Hydragel ISO-PAL K20 (PN 3022)
Hydragel 7 ISO-PAL (PN 4112)
Hydragel 15 ISO-PAL (PN 4132)
Regulation Number: 862.1050
Regulatory Class: II
Product Code: CIN
Dated: April 2, 2001
Received: April 11, 2001

Dear Dr. Janik:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K011113

Device name: HYDRAGEL ISO-PAL K20 (PN 3022)
HYDRAGEL 7 ISO-PAL (PN 4112)
HYDRAGEL 15 ISO-PAL (PN 4132)

Indications For Use:

All Sebia's Hydragel ISO-PAL kits are designed for the identification and quantification of alkaline phosphatase isoenzymes in human serum. The kits are used in conjunction with the manual electrophoretic chamber K20 or the semi-automated HYDRASYS electrophoresis system to obtain gels ready for interpretation.

Alkaline Phosphatase is an enzyme found in many human tissues. Elevated alkaline phosphatase is evident in a variety of pathological or physiological conditions involving liver, bones and several other tissues and organs. Measuring a quantitative value for alkaline phosphatase is effective in assessing severity as well as therapeutic monitoring. Quantitation of individual isoenzymes by densitometry of electrophoretic separations helps to identify the tissues responsible for the elevation.

Biochemical assays have been, and remain so, the most reliable means of detecting injury or metabolic changes in organs and tissues. However, no single biochemical marker can alone give a complete picture and extent of the changes. Therefore, the assay of alkaline phosphatase isoenzymes is often used in tandem with other assays.

To perform the test, each sample is applied in duplicate. In the course of electrophoresis on alkaline buffered agarose gels, one of the sample duplicates passes through a lectin deposited anodally from the sample's point of application. Under the conditions chosen for the electrophoresis, the lectin precipitates the B isoenzyme while other isoenzymes are virtually unaffected. This set-up allows the separation of otherwise co-migrating B, L1 and P1 isoenzymes. The separated isoenzymes are visualized using a specific chromogenic substrate. The dried gels are ready for visual interpretation. Densitometry of both tracks for each sample is required to obtain accurate relative quantification of individual zones.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Fred Lacy
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011113

Prescription Use ✓ **OR** **Over-The Counter Use** _____
(Per 21 CFR 801.109)